

## REMARKS

A Declaration is provided herewith by Dr. Howard Erickson. Applicants respectfully submit Dr. Erickson is “one skilled in the art” and is qualified to comment in the fields of equine anatomy, physiology, pathology and in particular, the condition referred to as exercise induced pulmonary hemorrhage. The presently pending claims are directed to EIPH and other conditions of equine physiology and pathology.

The Examiner rejected claims 22-46 and 48-58 under 35 USC Section 103(a) as being unpatentable over U.S. Patent No. 6,470,883 to Beaudry (“Beaudry”) in view of Applicants’ “own disclosure of Cook.” For the following reasons, this rejection is traversed.

At page 3 of the Office Action, the Examiner stated:

Beaudry discloses a nasal epidermal lifting mechanism positionable on skin of either humans or animals. The nasal dilator has an adhesive layer and a support layer having one or two support members 22. However, its use on horses to treat respiratory disorders or EIPH is not specifically disclosed.

Applicants disagree with the Examiner’s conclusion that Beaudry discloses the use of a nasal epidermal lifting mechanism in animals. Moreover, not only does Beaudry not “specifically disclose” use of a nasal epidermal lifting mechanism on horses to treat respiratory disorders or EIPH, Beaudry does not specifically, or generally, disclose the use of the disclosed devices for treatment of respiratory disorders of anything, human, horse, or other animal.

Beaudry does disclose devices used for a variety of purposes including:

...dressings for wounds, bandages, drug delivery systems, epidermal lifting mechanisms, and positioning mechanisms for positioning epidermal layers of skin on humans and/or animals in predetermined manner.

Beaudry at Col., lines 12-14. However, Beaudry does not disclose, teach or suggest a “nasal epidermal lifting mechanism” for animals. Everywhere Beaudry discusses an “epidermal lifting mechanism” that has any reference suggesting “nasal” application, it is specifically discussed in the context of use on humans. See for example: col. 1, lines 18-20 (“human body”); col. 1, lines 52-55 (“person’s nose”); col. 5, lines 8-10 (“person”); col. 5, lines 35-41 (“persons nose”); col. 11, lines 22-34 and FIG. 1 (referring to prior art nasal dilators for humans); col. 12, lines 4-13 and FIGS 7 and 15 (referring to a human nose); col. 12, lines 34-36 (referring back to FIG. 7 showing a human nose); col. 12, line 63-col. 13, line 10 (“persons nose”); col. 13, lines 52-57

(referring to “nasal passages” and FIGs. 15-17 showing only a human nose); col. 14, lines 23-31 (“persons nose”); col. 14, lines 32-52 and FIGs. 21 and 22 (referring to a “persons nose”); etc.

To the extent that the drawings of Beaudry provide any disclosure of a “nose”, all FIGs. are solely directed to a human nose. See FIGs. 15-17, 22, 26-30, 91 and 92.

Furthermore, Applicants direct the Examiner to the attached “Declaration of Howard H. Erickson DVM, Phd.” “Erickson Declaration” As discussed above, Dr. Erickson is “one skilled in the art” and qualified to comment on the present invention. Dr. Erickson’s credentials are set forth at Paragraphs 1-5. At paragraph 6 Dr. Erickson comments on Beaudry. In contrast to the Examiner’s position, Dr. Erickson does not understand Beaudry to teach or suggest use of nasal epidermal lifting mechanisms in animals, nor horses, as recited in the pending claims.

Thus, in contrast to the Examiner’s position, Beaudry does not disclose “nasal epidermal lifting mechanisms” for animals. Moreover, the anatomy of a horse (e.g., the facial shape as well as the presence of the equine nasal diverticulum) is unique as compared to most if not all other animals. Therefore, even if Beaudry could be construed to suggest a nasal epidermal lifting mechanism for use in “animals”, nothing in the reference teaches or suggests use for “horses” as claimed in the present invention.

As described above, the nasal epidermal lifting device disclosed in Beaudry is clearly designed specifically for use with a human nose. Applicants submit that in view of the structural and mechanical differences between human and animal airways, it cannot be assumed that what is effective on a human will be effective on a horse. Structural and mechanical differences between human and equine nasal passages are significant enough that what works on a human does not always work on a horse. Erickson Declaration at paragraphs 7 and 9. This is a reality in many situations when comparing human and horse anatomy. For example, a shoe for a horse would not be suitable as a shoe for a human.

In view of the foregoing, Applicants maintain that the Examiner’s reliance on Beaudry for teaching or suggesting use of nasal epidermal lifting mechanisms for an animal, is misplaced. Applicants traverse any rejection based on this erroneous presumption.

The Examiner maintained that the present invention is unpatentable as obvious over Beaudry in view of Applicants' "own disclosure of Cook." Applicants maintain that Cook, with or without Beaudry, fails to teach or render the herein claimed invention obvious.

Applicants agree that Cook hypothesized that EIPH was caused by asphyxia, and that

“...pulmonary edema will occur in any horse that has to breathe in against the abnormal resistance of a closed or partially closed upper airway defined as the airway between the nostrils and the windpipe”

Applicants note that the above quote from Cook, paraphrased by the Examiner, is incomplete and should read that the “upper airway” is “....defined as the airway between the nostrils and the windpipe *at the first rib*.” That is, the equine windpipe extends from the nostrils, through the head, past the throat and esophageal *os* down the neck and into the chest to about the first rib. Applicants agree that this large section of equine respiratory anatomy is the “upper airway” and notes that the same is stated in the Background section of the present disclosure

The Examiner went on to state:

“...One skilled in the art would recognize that nasal dilators are commonly used to hold open or open up blocked passages just above the nostrils.”

This statement, however, is true only for humans, there is absolutely no support for this statement as it applies to horses. Erickson Declaration at 4.

“Of course this would constitute or cause an abnormal blockage or partial restriction of the airway and therefore cause abnormal resistance to breathing....”

This sentence is unclear. In the Examiner’s statement what is the “*this*” that the Examiner believes would “constitute or cause an abnormal blockage or partial restriction of the airway”? The Examiner is requested to clarify before Applicants can fairly respond to any rejection based on this statement.

The Examiner then stated:

“...It would have been obvious to have used the nasal dilator of [sic] Beaudry on an animal/horse afflicted with EIPH, as Beaudry discloses that this increases the airway [sic] to the lungs.

Applicants note that Beaudry only discloses increasing airway to the lungs of *humans*, not horses or other animals. As previously discussed, any airflow benefit provided to a human from use of a nasal dilator does not make obvious that such a result can be expected in a horse for many reasons including anatomical differences between horses and humans. See Erickson Declaration at paragraph 7. Furthermore, Cook does not teach that EIPH can be reduced by increasing air to the lungs. Rather, Cook proposes that EIPH is caused by an obstruction in the upper airway.

Quoting the Examiner from page 4 of the Office Action, the “totality” of what is “disclosed [in Cook] is the overriding factor.” When read in its totality, Cook focuses only on an obstruction in the upper airway caused by “narrow throats and larynges” Thus, Cook teaches a different anatomical site as a possible cause for EIPH than the presently claimed invention. Moreover, Cook provides absolutely no guidance as to how to reduce EIPH caused by the blockage he proposed, and provides no basis for believing that merely supporting tissue overlying the nasal passages could reduce EIPH in horses. Erickson Declaration at paragraph 8.

The Examiner further stated:

“To use the device on an animal/horse afflicted with or susceptible to other known respiratory disorders would have been obvious as well to again increase the available air to the lungs.”

Again, any airflow benefit provided to a human from use of a nasal dilator does not make obvious that such a result can be expected in a horse for many reasons including anatomical differences between horses and humans. Erickson Declaration at paragraph 7. Moreover, neither Cook nor any other reference of record discloses use of an equine nasal support for ameliorating any other respiratory condition in the horse. Erickson Declaration at paragraph 9.

Applicants also disagree with the Examiner’s comments regarding use of “3 lift members” rather than one or two. However, because lift members are the subject of dependent claims, and because the dependent claims are patentable for at least the same reason as discussed for the dependent claims, further discussion is believed unnecessary.

Any claim rejection based on the Examiner’s comment regarding use of a nasal support device to reduce respiratory impedance is traversed for reasons previously discussed. See also Erickson Declaration at paragraph 6, 7 and 9.

### **Examiner’s “Response to Arguments”**

The Examiner stated that Applicants' prior arguments regarding non-enablement of the dilators of Beaudry were not persuasive and that Beaudry would lead one skilled in the art to “try the devices on any animal”. Applicants disagree for reasons previously stated. Moreover, the Examiner’s position is in direct conflict with the opinion of Dr. Erickson (Erickson Declaration at paragraphs 6-10). Dr. Erickson is one skilled in the art.

The Examiner then stated:

“There is no disclosure [in Beaudry] that would lead one to believe that the dilator when appropriately sized and then used on a horse would be inoperative.

More importantly under the law, however, nothing in the disclosure provides a teaching or suggestion that such a dilator would be *operative* on a horse.

The Examiner’s Response to Arguments pertaining to Cook, and Applicants comments thereto are as follows:

“The fact that Cook may have targeted the throat does not mean that the earlier broader description of the nostrils to the windpipe should be ignored. The totality of what is disclosed is the overriding factor.”

Applicants agree that Cook’s targeting of the throat does not mean that the definition of the upper airway should be ignored. However, disclosing one location within the upper airway as a source of problem is not a disclosure that teaches or suggests supporting a different location as claimed in the present invention. Erickson Declaration at paragraphs 8 and 9.

“Even though Cook may not have arrived at the same solution to treating the problem, the disclosure of Cook recognizes a problem and arrives at a theory for its cause.”

Cook does not arrive at the same solution to treating the problem claimed in the present invention. In fact, Cook does not arrive at any solution. Cook does recognize a problem and proposes a theory. However, the theory proposed does not render the solution claimed in the present invention obvious. Erickson Declaration at paragraphs 8-10.

“Cook may not have had the benefit of the knowledge that dilators for horse’s nasal passages were known.”

Applicants cannot comment on whether Cook knew of nasal dilator’s for horses or not.

“In, any event, Beaudry provides the impetus for using a dilator on an animal; the prior art is full of nasal dilators for horses (albeit the previous dilators were inserted into the nasal passages ) ...”

Although, as discussed below and recognized by the Examiner, nasal dilators were known at the time of Cook’s proposed theory, Cook failed to teach or suggest the use of known dilators for the condition proposed. Moreover, no reference of record teaches the use of prior art devices, or the presently disclosed nasal supports, for use according to the claimed methods.

The Examiner concluded by stating:

“...and therefore, the examiner contends that there is sufficient evidence that one skilled in the art would have found it obvious to have used a nasal dilator, such as that disclosed

by Beaudry, on a horse to treat EIPH or any other respiratory ailment caused or exacerbated by restricted airways.”

Applicants maintain that the Examiner has provided insufficient evidence to support his contention. Moreover, the Examiner’s contention is in direct conflict with the contention of “one skilled in the art.” (Erickson Declaration at paragraphs 4, 6, 7 and 9).

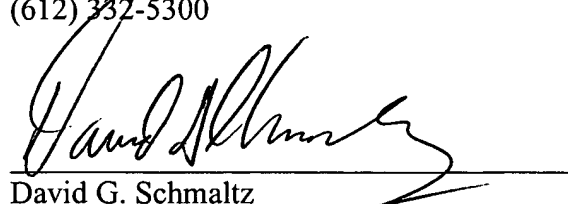
Indeed, even when one skilled in the art was given a device according to the instant invention and was taught to use the device according to methods of the invention, the invention was not obvious. Moreover, not only was the invention not obvious, Dr. Erickson was initially skeptical, and did not expect the benefits that he has now learned to be the case. Erickson Declaration at paragraph 10.

In conclusion, the Examiner has provided no reference that discloses the use of an externally applied nasal support device for horses, no reference that teaches or suggests that support of the nasal passages can reduce EIPH in horses, and no reference that teaches, suggests that an externally applied nasal support device can ameliorate other conditions of the equine respiratory tract. Accordingly, the Examiner’s rejection is traversed and a notice of allowance is earnestly solicited.

Respectfully submitted,

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